DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUL 12 2004

2004 JUL -6 P1:54

Nancy L. Buc
Carmen M. Shepard
Buc & Beardsley
919 Eighteenth St., N.W.
Washington, D.C. 20006

Re: Docket No. 2004P-0015/CP1

Dear Ms. Buc and Ms. Shepard:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition submitted on January 9, 2004. Your petition requests that the Agency deny approval of any new drug application for recombinant salmon calcitonin nasal spray for prevention or treatment of osteoporosis that contains as proof of efficacy bone mineral density data or other markers of bone cell activity but lacks clinical data demonstrating the efficacy of the product in treating or preventing bone fractures.

We have been unable to reach a decision on your petition because it raises significant issues requiring extensive review by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2004P-0015

LET 1